What's Wrong with Importing Drugs from Canada?

A National Symposium
on Drug Importation

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Introduction

By Joseph L. Bast[1]

The National Symposium on Drug Importation took place in Chicago on October 23, 2003. Eight speakers from Canada and the United States presented every side of the debate over the course of a half-day program. Their presentations were transcribed and are presented in this booklet.

The four experts on drug importation from leading think tanks who agreed to come to Chicago to speak were Stephen Entin, president of the Institute for Research on the Economics of Taxation; Robert Goldberg, a senior fellow with the Manhattan Institute; John R. Graham, director of health and pharmaceutical policy research at the Fraser Institute in Vancouver, Canada; and Grace-Marie Turner, president of the Galen Institute.

Also invited were 26 people from government and leading business groups, including 12 from Illinois Governor Rod Blagojevich's office. Four of them said yes: Sean Heather, executive director of Congressional public affairs for the U.S. Chamber of Commerce; Senator Chris Lauzen, who represents the 25th Senate District in Illinois; David Miller, president of the Illinois Biotechnology Industry Organization; and Senator Steve Rauschenberger, who represents Illinois' 22nd Senate District.

Approximately 80 people attended the symposium over the course of the day, including state legislators, pharmacists, small business owners, trade association lobbyists, the president of a drug importation business, and at least one member of Gov. Blagojevich's staff. Lively question and answer sessions followed each of three panels.

About the Issue

Drug importation is getting national attention. During the week of the symposium, the *Washington Post* ran a front-page investigative series on the subject. The first article in the series was titled "U.S. Prescription Drug

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System Under Attack," and began with the following warning:

> For half a century, Americans could boast of the world's safest, most tightly regulated system for distributing prescription drugs. But now that system is under-cut by a growing illegal trade in pharmaceuticals fed by chemical profiteers, unscrupulous wholesalers, rogue Internet sites and foreign pharmacies.

The State of Illinois is interested in drug importation because it spends a lot of money on prescription drugs: about $340 million a year on its own employees and its retirees and approximately $1.5 billion each year on Medicaid, for a total of $1.8 billion a year. So, under the direction of Gov. Blagojevich, the state is looking for ways to reduce its spending on prescription drugs. One way under consideration is to import less-expensive drugs from Canada and other countries.

The governor named two "special advocates" to study the issue. Their study was scheduled to be released on October 20, and Heartland's National Symposium was scheduled to respond to their findings. Unfortunately, the study's release was delayed until shortly after the conference. While the study's authors strongly endorse importation, and the governor has cited it in defense of his proposal, the study itself fails to contradict or does not address the objections raised by importation opponents who spoke at the symposium. Two appendices at the end of this book—one written by me and the other by William K. Hubbard, associate commissioner for policy and planning for the Food and Drug Administration—comment specifically on the governor's report.

About The Heartland Institute

The Heartland Institute has been addressing health care issues since 1993, when I had the opportunity to coauthor a book titled *Why We Spend Too Much on Health Care* with Dr. Stuart Wesbury and Richard Rue—a book still worth reading, I might add, despite changes in the debate that have taken place since 1993. We launched *Health Care News*, Heartland's monthly publication on health care, in March 2001.

The Heartland Institute is a 19-year-old nonprofit organization based in Chicago. Heartland is a national organization that provides quality information on a wide range of topics to the nation's 8,300 state and national elected officials. It sends every elected state and national official

in the U.S. four monthly publications: *School Reform News, Environment & Climate News, Health Care News,* and *Budget & Tax News.* Among state legislators, we are the best-known think-tank in the United States: 86 percent recognize us; 60 percent view us as a valuable resource.

Since it often comes up, let me mention quickly how we're funded. The Heartland Institute has 1,400 donors. No one donor gives more than 5 percent of our annual budget. We do receive funding from the pharmaceutical industry; exactly one gift this year. It arrived in January. It was for $55,000 and it came from Pfizer. It was earmarked for *Health Care News* and we promptly spent it on the January and February issues of *Health Care News*.

We did not solicit funding from anybody for this conference; it was funded out of general operating support. So, I'd like to thank the 1,400 donors to The Heartland Institute, many of whom don't care about this issue, or have contradictory views about this issue, for nevertheless allowing us to spend their money to hold this conference today.

Not a Solution to State Budget Problems

By Senator Steve Rauschenberger[2]

Everybody relax a minute. It's just a state senator up here. This is not a policy expert!

I'm very, very interested in being here and happy to be able to participate, but somewhat reluctant to go first. It's always easier for people like me sometimes to hear the policy experts and then react.

I'll try to give you my impressions as a policy maker who has spent 11 years on the Senate Appropriations Committee. I've specialized in Medicaid funding, and have had the opportunity to work on pharmaceutical acquisition issues for the state of Illinois intensively for eight years. But, I certainly don't have the economics background of the other panelists you're going to hear. So, I'll ramble a little, try to draw some points and some conclusions and try to maybe illuminate the question from a political point of view and then turn it over to the policy experts, who I'm sure will follow up and give you better data.

Not a Real Solution

What we're embarked on in Illinois is no real solution to a problem we really do need to talk about. Illinois' challenge, our budget challenge, does not revolve around pharmaceutical issues. It revolves around stewardship and our revenue streams. It is so easy and dangerous for governors and politicians in general to politicize things and take the easy path and argue that the solutions to their problems are somehow vested in multimillion-dollar companies that are obeying the law.

Illinois has the country's most comprehensive senior and low-income support system for people who need access to pharmaceuticals. To argue

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[2] Sen. Steve Rauschenberger has represented Illinois' 22nd Senate District since 1992 and currently serves as Assistant Minority Leader. He received his bachelor's degree in business administration from the College of William & Mary.

that access is a problem in the state of Illinois is to argue it must be an even worse problem in other states. We have acted aggressively in the General Assembly over the last four years to make sure that means-tested programs are in place for seniors up to household incomes in excess of $25,000 based on net tax earnings. So, there are programs in place to make sure pharmaceuticals are available and stay accessible.

Governors and other elected officials who argue that importing Canadian price controls into our market-driven system is in either the short-term best interest or the long-term best interest of Illinois consumers or federal and state governments are wrong. And I think people have to stand up and talk about that. We have a system in the United States that is the safest in the world. Safety and certainty and efficacy have always been the hallmark of the FDA's approach to the whole pharmaceutical industry. We force drug companies to spend hundreds of millions of dollars researching and jurying the products they want to bring to market, both for their effectiveness and their safety.

Impact on Research and Development

Drug companies have been engaged in a 50-year search for the next compound, the next therapy that will make a difference in Americans' lives. The entire world benefits from the progress made in American pharmaceuticals. To argue that we ought to use arbitrary price controls established by other countries as a basis for establishing—essentially, through market mechanisms—pricing in the United States is to walk away from our commitment to protecting the intellectual property that's been discovered by the pharmaceutical companies.

If we're satisfied that we have now discovered every compound we want, we have solved every health problem that we're willing to work on, we can just simply expropriate the intellectual property of drug companies and end the whole idea of research. If you won't pay people to do research, to do testing, to do evaluation and to do discoveries, don't expect them in a market-based economy to be willing to engage in that.

As European countries and the Canadians have imposed price controls on the prices of pharmaceuticals in their countries, less and less research is done anywhere but in the United States. The latest numbers I've seen show that well over 80 percent of all the pharmaceutical inventions and breakthroughs in the past 10 years have taken place in the United States,

mostly by companies seeking to find a compound that does something they can sell for a profit in the marketplace.

It's important that drugs be affordable, but it's also important to have that next generation of drugs. If we're not willing to be committed to that, we really are doing our children a massive disservice. I think we ought to face up to that. The governor of the state of Illinois was willing to borrow $10 billion on an arbitrage scheme in the market and allow my 20-year-old son at the age of 49 to pay that off. He and other public officials apparently are willing to risk the investment that the pharmaceutical industry makes in research and development in some kind of short-term stampede to hide their budgetary problems under the blanket of lower pharmaceutical prices.

To argue that state government, as an organized entity, ought to be pursuing things that violate the FDA-regulated distribution chain, that violate our trade agreements, and that violate federal law, seems to me to be either a misguided notion by a chief executive who doesn't know his fundamental responsibilities or an effort to hide the ball at a very difficult time for state leadership.

Real Solutions

There are real solutions available to Americans for the issues concerning prescription drugs, and I think those ought to be the focus of discussion. But, seemingly, the same people arguing for Canadian price controls being imported in the United States are unwilling or unable to deal with the real fundamental problems that drive up the cost of pharmaceuticals in America.

We need fundamental court reform in the United States. The class-action lawsuits and the tort system drive up costs for all large manufacturers, in particular people making sensitive and groundbreaking innovative products. We have the most expensive tort system in the world. I know there are people on the other side of the aisle from me in politics who find that untouchable. You can't raise that issue, because it affects their basic support base. But, if we want to talk about real relief and pricing from the general public, we need to talk about court and tort reform and we need to be honest about it.

We need to talk about speed-to-market reforms. We need to take a look at what part of FDA testing really is efficacious and makes sense and which part slows our speed to market. We need to have that done, though, by researchers who aren't being politically pressured. Some drugs obviously

should be moved to market faster if they're lifesaving and the risks are worth shortening the process. Other countries bring pharmaceutical inventions to market faster and we need to see if they've discovered some shortcuts that would reduce the unnecessary costs we have imposed on our pharmaceutical research companies.

We need to be honest about taking a look at utilization review. Something like 75 percent of all Ritalin prescribed in the world is prescribed in the United States. We are a country that has to face up to the fact that if we're going to use 75 percent of the world's pharmaceuticals, we're going to pay for at least 75 percent of the world's pharmaceuticals.

I have been witness to state agencies refusing to turn over records for industry-requested efforts to take a look at utilization review. We have people in the Medicaid system who are now receiving seven, eight, nine, and ten prescriptions each month. In some cases that may be entirely appropriate, but it ought to also be entirely appropriate to make sure a practitioner who understands the interactions of pharmaceuticals is looking at that cocktail mix of pharmaceuticals they're taking to make sure we don't have two or three medical providers prescribing conflicting drug regimes. So governments, like our state, that want to lower spending ought to be taking a hard look at the utilization review.

We, in state and federal government, need to take a look at means-tested support. We need to make sure pharmaceuticals are accessible to people in the United States who have problems affording them. We need to stay committed to that. And we need better regulation of our wholesale market. We need to make sure people purchasing drugs for use in hospice and nursing-home care are not reselling those drugs in the marketplace and putting the safety of that system at risk.

And we need a more fundamental effort at generic awareness. Much of the individual consumer's drug bills can be affected if they take a hard look at generic alternatives. Those are real solutions to a real problem that do not undercut our opportunity to have future innovations.

Most of all, we have to encourage consumers to be responsible about their health care. There is no quick fix on the Web. If the drug's not prescribed, you ought not to be ordering it. We ought not to encourage people to self-medicate. We're seeing more and more abuses of that. There are people on the Internet willing to prey on Americans' desire to find the pill that solves all their problems. And that's fundamentally a flaw we have in our society.

I think we need to be very cautious when we talk about changing public policy in this area. We should be honest about the value of intellectual property and what research means to future generations, and we ought to be very deliberate in our efforts. We also need to keep this issue in perspective. Drug importation is not a solution to the state budget any more than the Illinois lottery or riverboat gaming were. To say Canadian-style prices would solve Illinois' problems is untrue. We need to be committed to making sure we do the right things.

The Danger of Unknown and Unknowable Costs

By David Miller[3]

The points that are going to be made today about the safety and economics of drug importation as they relate to pharmaceutical issues and products are even more applicable to biologics: vaccines, therapeutic serums, and other biological products used to induce immunity to infectious diseases or harmful substances. In this field, investment in research is much heavier and concerns about safety and intellectual property rights are all the more severe. So everything the learned people up here say about the safety and the economic aspects of importation can be doubled or squared when applied to biologics, which are more and more coming into play as solutions to health problems, problems we could not have solved prior to biotechnology's arrival on the scene.

What Is iBIO?

The organization I represent, iBIO, came about with the joining of two organizations, the Chicago Biotech Network that was active here in Chicago, and a bigger not-for-profit, known as IBIO, with large organizations as members, such as Monsanto, Pfizer, and the Illinois Soybean Association. They merged in 2001 to become the Illinois Biotechnology Industry Organization, or iBIO. We became the advocate of the life sciences in Illinois. We are also an affiliate of the national BIO in Washington, DC.

Some of our members, such as Abbott, Johnson & Johnson, and Pfizer, are household names, as are IBM Life Sciences and Deloitte & Touche. But in addition to them and the major universities you see in the list are many companies you've probably never heard of. These small companies are trying to get their start here in Illinois, using the tremendous amount of

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[3]David Miller is president of iBIO, the Illinois Biotechnology Industry Organization, headquartered in Chicago, Illinois. Prior to joining iBIO, Miller served in business development executive positions for technology startups. His email address is dmiller@ibio.org.

science that's generated at our many research institutions, including some of the top research institutions in the United States.

We think of the big biotechnology centers as being San Francisco, San Diego, and Boston, but the reality is that pharmaceutical and biological firms in Illinois, according to a late 1990s Harvard School of Business study, employ close to 58,000 workers. So you're talking about nearly 60,000 workers connected with this industry.

iBIO's mission is to secure for Illinois and the Midwest recognition as one of the world's great life sciences centers. And because we believe in operational definitions, we define that as a great place to do business if you're a life sciences company and a great place to start new businesses. We want to help turn life sciences research into new companies, new wealth, new jobs, and new opportunities to contribute to solving the world's ills right here in the Midwest.

And finally, we want to use the special properties that Chicago enjoys to secure for the Midwest greater interaction with international firms and international efforts in biotech and in life sciences. Takada, Japan's number one pharmaceutical company, which is very interested in biotechnology and which has the sixth biggest market cap of any company in Japan, has its U.S. headquarters right here in Chicago. Fujisawa, the number six pharma company in Japan, also has its U.S. headquarters here in Chicago. Both are iBIO members trying to help us push that part of our program.

Difficult Questions

For my presentation, I want to pull together, under the rubric of management, some of the ideas that others are going to be talking about. As a student of management, one of my heroes for the last 10 or 12 years has been Dr. W. Edwards Deming, who died not too long ago. He taught quality to Japan and in later years taught it to the United States.

One of Deming's favorite quotes was "the most important figures needed for management of any organization are unknown and unknowable." What's the value of a happy customer? What's the cost of an unhappy customer? It's difficult to gauge those things. I'm going to talk today about some of the unknowns and unknowables concerning drug importation, questions that are difficult to answer with legal citations or with available economic studies.

First of all, what's going to be the cost of enforcing criminal actions

against bogus drug dealers and counterfeiters? Those of you who have been following the *Washington Post* series know that our drug system is already under attack by importation by just these kind of folks.

What's going to be the legal cost if we give these criminals greater access to our system? What's going to be the cost of taking care of citizens injured by poorly manufactured or otherwise unsafe drugs? Commissioner McClellan of the FDA, who's both a PhD and a doctor, says, "a cheap drug is not a bargain if it puts your health at risk." There's an unintended and costly effect of getting cheap drugs.

Even in today's system in the United States, which is the safest in the world, there are billions of dollars in costs incurred due to adverse effects from not having quite the right dosage, not having quite the right kind of indications, and so on. When you open that system up to imports from Ecuador, from India, from Pakistan, which are going to flow through Canada, because Canada does not produce much in the way of drugs, you're really making an existing public health problem much worse.

Third, what's going to be the cost in lives and dollars here in Illinois if we suffer a terrorist attack through Canada? You heard what the *Washington Post* had to say. It's a very real possibility. The folks who engineered 9/11 have the money and the technical talent to do just that, particularly if we open the doors in the way the governor suggested.

Fourth, what's going to be the cost to the state if the importing agencies have to fight federal and civil and criminal charges? Some of what the governor has proposed is a violation of the civil law, and if it was done with intent to violate the civil law it becomes a criminal matter. Are we going to hold those folks harmless? Are we going to spend Illinois tax dollars to defend them? What's that going to cost?

Fifth, what's going to be the cost to U.S. patent holders if a major U.S. industrial state contravenes the patent rights of an important industry segment? Make no mistake; this proposal contravenes the patent rights of those companies.

What's going to be the injury to our North American free trade protocols, so hard fought for, if a major U.S. state contravenes—or more accurately, puts Canada in a position of contravening—the provisions of NAFTA? Because the provisions of NAFTA state clearly that no state should take away the intellectual property or otherwise confiscate the property of companies or the parties in another state.

Next, will the governor hold harmless drug manufacturers from lawsuits

alleging unsafe drugs after the manufacturers' loss of control over the quality of those drugs? We have a very active and aggressive plaintiff's bar and in my lawyer days, I used to deal with them. They're going to go after these folks, and with the companies having no control or radically losing control over the viability of their own drug source and supply chain, which is safely controlled here in the United States, they're going to be sued.

Is the governor going to protect them from suit? Is he going to hold them harmless? What's that going to cost? What's it going to cost our court system?

Impact on Business Climate

What will it cost Illinois for creating a hostile business atmosphere and vilifying a major industrial group—an industrial group that is creating about 60,000 jobs in this state?

What's that going to do to iBIO's work of trying to encourage new companies to start here? What's it going to cost us in jobs? What's it going to cost us in tax dollars? What's it going to cost in terms of our ability to contribute to solving some of the world's hunger, malnutrition, and disease?

What are the implications of a plan that essentially assigns an important element of U.S. sovereignty to another government?

Historically, the United States has been very protective of key industries. For example, it has sought to maintain domestic industries that supply our defense system, thinking that if we run out of steel, we don't want to rely on even friendly countries like Japan and Sweden to provide steel for our military, so we protected those industries. How much more do we want to protect what we actually put in our bodies? And yet, we're going to trade our sovereignty in this area to Canada, to Ecuador? We're going to trade it away to India and Pakistan? I don't think we want to do that.

What's the total cost now—getting back to Deming's point—what's the *total* cost, not just the price tag, of this plan to the citizens of Illinois and to the United States, beyond the savings on a given prescription drug, taking into account the answers to these questions I've been asking? Because it's not just the price tag on the drug, it's the total cost of a system that's proposed for radical modification.

Small Gains, Enormous Risks

By Robert Goldberg[4]

The focus on finding ways to reduce spending on prescription drugs has turned attention away from some important facts. One fact is that spending on drugs is actually a very good investment. For every dollar that you spend on new drugs, according to a study by Frank Lichtenberg, an economist at Columbia University's business school, you save $6 in other medical expenditures in treating that disease.[5] So spending more on prescription drugs is actually a very wise investment.

A second fact is new medicines yield better results than older medicines. Newer and better drugs just don't get launched as early in Canada as they do here. Fusion, which is a new drug for AIDS, just got approved in Canada a couple of days ago. It was approved here in the year 2001. The new drug we heard a lot about to reduce the repeat odds of breast cancer, Femara, was approved in the United States, I think, in 1998. It was approved in Canada in 2001, and so it goes. So as far as importation is concerned, you're always going to be importing older drugs all the time, if at all.

Problems with Cheap Drugs

According to the principal proponents of importation, Joanne Emerson and your local congressman, Rahm Emanuel, if we brought in importation, a lot of the stuff the *Washington Post* article has been talking about, such as the

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[5] "The Benefits and Costs of Newer Drugs: Evidence from the 1996 Medical Expenditure Panel Survey," NBER Working Paper No. 8147, October 2001.

purchases of drugs from foreign Internet pharmacies, would cease since we'd have an adequate supply of safe and effective medicines here in the United States. So people would stop buying drugs from foreign Internet pharmacies since it would be a wide, cheap source of drugs here in the United States.

And you know what? They're right. You'd be able to buy a lot of these drugs over American-based Internet pharmacies like I did. I bought this bottle of Vicodin, a powerful and habit-forming pain killer, over the Internet without a prescription from a pharmacy based in Pembrooke Pines, Florida. Actually, I didn't buy it: I had my 16-year-old son Zack type in his exact age, weight, height, and use my credit card to buy prescription-strength Vicodin. He also bought OxyContin, which is coming in a couple of days, and Flexeril, which is a muscle relaxant, some steroids, and some other stuff. All through an American-based Internet pharmacy.

So Congressman Emanuel is absolutely right. We're not going to need those second-rate, foreign-based Internet pharmacies. We're going to have our good old American pharmacies buying these drugs from overseas and packaging this stuff, and getting their own markups and pocketing the difference, and selling it to my kids, and making a good old American profit.

Here's the hidden truth about importation. What it will do is shift the profits of this vast, criminal, illegal, and unsafe enterprise from overseas into the United States. It's already happening and will just gather steam if we do that. To suggest it won't happen, that somehow importation will make the sale and purchase of drugs from overseas safer, is not only irresponsible; it is intellectually dishonest.

Where Canadian Drugs Come From

Some people in Congress and your governor are suggesting we can confine importation to Canada, because we know Canada's drug safety regulations are on par with the United States. It's a safe, secure source of prescription drugs, right?

How many of you know Canada gets 60 percent of its prescription drugs from the United States? It makes only a very small percentage of its prescription drugs for internal consumption, and then it gets the rest of it from around the world. Most of the drugs coming into Canada are under a personal use exemption that allows people to bring in commercial quantities

of these products without any inspection from Health Canada whatsoever. And it still can come in from the United States without any inspection from Customs or FDA. Under Congressman Gutknecht's bill, that amount could be of any amount brought in by any individual, any wholesaler, any distributor, without any inspection by the FDA. In fact, the FDA would be prohibited from requiring such inspections.

As more of us buy drugs from Canadian pharmacies, where do you think Canada will turn for new supplies? I bought a tranquilizer a few months ago from a Canadian Internet pharmacy. The drug that arrived came not from Canada but from Namibia, which is nowhere near Ottawa but in Africa.

Now, that's not surprising because it turns out that in the first eight months of 2003 there has been a huge increase in pharmaceutical imports into Canada from other countries. (See table.) Many of these countries are not friendly to the United States and do not have high-quality pharmaceutical industries, leading us to wonder exactly what it is they are sending to Canada and where, in turn, they are getting these drugs from.

Increase in Drugs Imported by Canada During the First Eight Months of 2003

Country	*Percent increase*
China	430%
South Africa	369
Turkey	160
Iran	65
Saudi Arabia	90
Philippines	140
Bangladesh	1300

A country that is importing more drugs from other countries and exporting more to us is doing one of two things. Either those drugs from Iran and Saudi Arabia are staying in Canada and poisoning their people, or they're shipping them here. Anyone want to wager a bet as to which it is?

So the idea that the State of Illinois ought to start buying drugs from Canada amounts to aiding and abetting the importation of adulterated and contaminated medicines from countries like Iran, Saudi Arabia, and Bangladesh. That's objection number one. Objection number two is that we are making it easier for people like this to sell drugs to my son on a daily and increasing basis by exploiting weaknesses that already exist in the U.S. drug system's security.

You may save a little bit of money in the short run by allowing drug importation, maybe 2 percent. That's what the Europeans have saved with their parallel importation programs, and what the Congressional Budget

Office said we'd save on a government level. According to an audit of importation figures in Europe by IMS Global Health, the actual savings on the prescription drug side in Europe is only 1 percent.

But the price you're going to pay is allowing people who really don't care about public health and really don't care about saving money to profit at the expense of the drug safety and public health infrastructure of the U.S. That system is not perfect, but it has provided American consumers, pharmaceutical companies, and physicians with the opportunity to prescribe medicines with a high degree of safety and integrity. Drug importation is going to undermine the ability of drug enforcement agencies, U.S. attorneys, and the FDA to track down criminals like this.

The Dubious Economics of Drug Importation

By Stephen J. Entin[6]

It's a pleasure to be back in Chicago. I got my training down the coast a couple of miles at the University of Chicago. I feel like I'm bringing coals to Newcastle. What I'm about to say is really based on fundamental price theory, the sort you'd pick up in any textbook, and a little bit of corporate finance tossed in.

I'm not making it up. If you want to pick up one of the textbooks, you'll see the same sort of analysis. I'm just trying to apply it to a part of government policy where very frequently the budget people are involved or the social people are involved, but sometimes the economists aren't consulted. So this is a plea for a little bit of economic input into a difficult issue.

This is basically what we do at the Institute for Research on the Economics of Taxation, although usually at the federal level. We advise members of Congress and their staffs on complex issues, and I do a lot in federal budget work and federal taxation, as well as industrial policy.

We're talking today about a specific problem with the reimportation—or more accurately, the importation—of prescription drugs from abroad. Not all drug importation. As you know, we get some of our drugs from American subsidiaries abroad and from major foreign drug companies, made in plants inspected by the FDA. These drugs are imported under the companies' auspices in the normal course of their business, carefully controlled and distributed here in their normal manner at the normal U.S. prices.

The issue we are talking about today is the importation of cut-rate drugs produced outside of this system, some of which are indeed real drugs and

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[6] Stephen J. Entin is president and executive director of the Institute for Research on the Economics of Taxation (IRET). Entin was deputy assistant secretary for economic policy at the Treasury Department in the Reagan administration. His email address sentin@iret.org.

some of which are not. I'm going to focus on what we should be thinking about as people are talking about cut-rate imports of real drugs. Even if we are getting safe and effective products, would this be a good policy?

Crippling Research

Bringing drugs in from abroad at cut-rate prices would certainly seem to save current drug users money and seem to reduce benefit costs for this state's employee health plan. But if it worked, and if it spread to other states, and was copied by the general public, it would have a devastating side effect. It would cripple research into new medicines which are very expensive and risky to develop. It would cut off new and improved treatments to tens of millions of future patients, resulting in earlier death and reduced quality of life compared to what these patients could expect if the rules laid out by current law were followed. If governments want to help the poor or trim their payroll costs, importing price controls for pharmaceuticals is not the way to go about it.

Let's put the issue into perspective. New developments in biology and chemistry have opened up amazing opportunities for progress against heart disease, cancer, Alzheimer's, and viral diseases of all sorts, including AIDS. The human genome has been deciphered. Scientists are learning how to tailor a drug to the specific genetic makeup of a cancer patient's tumor. We know more today about cell chemistry than ever before.

You'd think that society would be urging the research community to take full advantage of these scientific advances by turning them into pills and treatments as fast as possible. Instead, the public and the politicians are obsessed with the cost and affordability of existing medicines and existing treatments.

Their knee-jerk reaction is to impose price controls or to let people import drugs from abroad where other governments have set low prices, or to demand discounts for patients in their states or in specific federal programs. The direct result of ratcheting down the returns on drug development will be to slow the rate of scientific advance and to delay the introduction of new medicines and treatments made possible by the new science.

Access to Drugs for the Poor

The ability of poor Americans to afford medication is a legitimate concern, but drug affordability is a welfare issue arising because some people have low incomes. It is not a problem with the price of the drugs. The right reaction is to leave the drug prices alone and to give the poor the wherewithal to purchase the medicines they need like everyone else. We should treat them with respect to their medical needs the way we treat them when they need to buy food: we give them food stamps; or when they need to buy housing: we give them housing vouchers. We don't put price controls on the food industry, nor do we routinely impose rent controls, except in a few cities with absolutely disastrous results.

What do you think would happen if we tried to help the poor buy food by telling the grocery stores they would have to sell everything at 30 percent off; or if we told the farmers they would get only half of what they now get for corn and wheat and soybeans? Many farmers would go broke. Many grocery stores would shut down. The food supply would shrink until there was enough of a shortage to drive the prices up so that, even with the discount, there would be as high a return to the suppliers as before the intervention to justify production.

So instead of price controls on food, we give people food stamps and let them go to the grocery store like everyone else. We fix the income problem without disrupting the price signals that make the market work. Similarly, if the state, or a company, has negotiated a health insurance package as part of its labor contract, it should honor that contract without trying to distort market prices. The employees and employers should take account of the costs when workers ask for health care benefits as part of their compensation rather than cash, and both sides should pony up and pay the market price. They should not gang up on the suppliers when they get the bill.

In a normal market, the prices of goods and services cover the costs of producing them. When you buy a loaf of bread, you're paying for the seed and the farmer's time, for the shipment of the wheat to the silo and from the silo to the mill. You are paying the wages of the people who work in the mill, of the people who bake the bread, and of the people who transport it and put it on the grocery store shelves. You're paying all of the costs of producing the bread.

The same thing is true for drug research. Consumers pay for what they get and get what they pay for. If we are not willing to make the patients pay

for the cost of their medicine, including the necessary R&D and testing that make possible the pills they consume, then some other way of letting the drug innovators recover their costs will have to be found or the research will stop. You might have to have the government come in and start subsidizing all the research, in which case either the politicians or the bureaucrats would probably start picking and choosing which pills to work on.

I don't think the result would be a good market outcome. The taxpayer would have to cough up the shortfall in drug revenues, or we would not get the research done; we would not get the scientists trained and hired, or the lab equipment and chemicals purchased for the research and the production of the medicines.

Why the Drug Industry Is Different

In most industries, competition sets the price of an extra unit of the product at the marginal cost of production. And in most industries it costs more to produce more units, so that the marginal cost is rising and exceeds the average cost by enough that the resulting price covers all the fixed costs.

In a few cases—and pharmaceuticals and software are two good examples—the competitive market price doesn't cover the research costs because the cost of an additional unit is very low and flat. The product can easily be reproduced without straining resources. With that cost structure, there are high fixed costs and flat or low marginal costs, and the normal market outcome—price equal to marginal cost—does not work well for these industries or for their consumers.

It may take a billion dollars of research to test thousands of potential chemicals for use against a disorder. One must find the few good candidates for development, test them for efficacy and safety, settle on the best, and develop a reliable and efficient manufacturing process to turn it into a marketable medication. Once the drug is perfected, however, it may cost only a few pennies to churn out an additional pill.

In this situation, the marginal cost will not cover the R&D costs. The product will be developed only if the discoverer can obtain a patent or a license giving it the exclusive rights of production for a time. The firm can then charge enough for a while to recover its development costs for that drug, including all the dead ends it had to explore before it could find the right route to the solution.

If, instead, other companies are allowed to come right in and copy and

sell the product at the cost of an additional pill without any of the development costs, then the cost of the original research is much harder to recover, research is discouraged, and it will not be undertaken at a socially optimal rate. It was precisely to deal with such cases that patent protections were instituted by civilized governments around the world.

The Importance of Patents

Patents allow innovators to charge enough to recover development costs and to earn a normal return on the investment. Then when the patent expires, the good is opened to competition and the price is driven down to the competitive level. Innovation is fostered, but the consumer is protected longer term by the expiration of the patent. The drug reimportation bill that was introduced into Congress a while back, and these other schemes to get around normal pricing structures, would effectively cripple patent protection and would violate the intellectual property rights of the innovators.

The patent process involves striking a balance. Longer patents would increase the incentive to innovate, which helps future consumers by creating new and better products, but it would increase the cost to current consumers. Shorter patents, or patents rendered ineffective by reimportation, would hurt innovation and the consumers who would benefit from it, but help current consumers in the short run. Patents, therefore, have a clear economic purpose. If the politicians and the public think they don't, that they are the result of some bizarre political clout and that they can be dispensed without consequences, they're wrong.

If drug companies have to charge enough to cover R&D, why do they sell drugs so cheaply abroad? You can find this in the textbooks too. The drug companies sell abroad at the reduced prices set by foreign governments because those governments set the prices just above the marginal costs of making additional doses. The resulting little bit of net revenue is better than none, so the companies will sell them product. The skimpy foreign profit margins, however, are not enough to contribute meaningfully to covering the fixed costs of the R&D or of setting up the production lines. The same is true when the companies sell for just over marginal costs in poor countries where a higher price would put the drugs out of the consumers' reach.

Consumers in rich developed countries with socialized medicine and

price controls are shirking their responsibility to help fund medical research. They are free riders on the strength of the U.S. market. The United States is the only country where the companies earn enough to pay for the fundamental science, the dead ends, the testing of the compounds that do not pan out, and the tests for safety and efficacy demanded by the FDA. As irritating as that is for American consumers and for the politicians who have promised drugs for the poor, and are now faced with having to pay for them, the alternative is not to have the drugs at all.

Unintended Consequences

If some states try to mimic the foreign freeloaders and arrange for their state governments and residents to duck their share of the nation's drug costs, then those costs will have to be picked up by other states and other U.S. consumers, or by the federal taxpayers, or the drugs will not be developed. If some states get away with being free riders, others will follow. And if everyone wants to be a free rider and no one picks up the slack, then there will be no new drugs.

Today we're talking only about Illinois and only about Illinois's public employees health benefit plan as the starting point. But the ultimate objective of most of the people supporting free importation is to drive down the cost of drugs throughout the country, so this discussion is part of a bigger issue. But let's look at Illinois just for a minute.

Suppose millions of Americans try to buy cheaper drugs from Canada. Canada's population is about 11 percent as large as the U.S. population, but its GDP is only about 7 percent of total U.S. income, and Canada spends less than 5 percent of what we do on drugs.

Suppose even 5 to 10 percent of U.S. customers started buying medicine from Canada in a particular case where the drug price happened to be lower in Canada. The U.S. demand would easily gobble up the whole supply of the drug that the company normally ships to Canada or produces there. There would be none left for the Canadians.

If you think that Illinois is only a small part of the United States and therefore only a small part of the problem, think again. The population of Illinois is about 4.4 percent that of the U.S., but it's equal to 40 percent of the population of Canada. Illinois's GDP is about 4.7 percent of U.S. GDP, but it's about 67 percent of Canada's. And given the higher rate of spending on drugs in the United States, the Illinois drug market is about 90 percent

of the Canadian drug market. Even if the governor's importation proposal for the state employees' health plan covers only the state employees' share of the state population, it would still absorb between 1.5 and 2 percent of the Canadian drug supply.

If all the states did that for their employees, you'd take almost 50 percent of the Canadian drug supply. Or if the practice spread to the rest of the Illinois population, to the seniors, to the local government employees, to the teachers and so forth, you can see there would be a significant impact. And if the other states followed suit, it would be even greater.

Markets Won't Allow It

Would the U.S. drug companies be willing to increase their shipments to Canada to cover the extra drugs being brought back to the U.S.? I don't think so. It would make no sense for them to do that. So there would be no medication left in Canada. Some Canadian newspapers are already catching on to that problem. Of course, Canadians wouldn't just sit there and let the drugs leave the country, and I don't think they are going to want to have to buy their drugs from Bangladesh and Iran. So they would have to start policing the border.

It would not be rational for a U.S. drug company to expand its foreign sales to make up for drugs imported to the United States at cut-rate prices, thereby pulling the rug out from under their own feet. They'd be much more likely to simply note that the foreign markets are not that big, and it would be better just to give them up, rather than to sell to them and destroy their pricing structure in the huge U.S. market. Therefore, these importation schemes really can't work. One way or another, the market is going to say, "This doesn't make sense, and it can't happen." And if it can't happen, we shouldn't do it.

Sooner or later we have to find a way to make other customers step up to the plate and do their part for medical research. Other nations need to do a better job than they are of supporting scientific advances. But until then, let's not destroy the work that is being done to fight disease and to improve the quality and length of life.

The bottom line: If we were to import price controls from Canada or Europe, we'd shut off the pipeline of new drugs. We'd be surrendering millions of American lives to ancient biological enemies that we can now defeat. We would be snatching disease from the jaws of victory.

Everyone knows the old saying about economics being the dismal science. Actually, economics is not the dismal science if you have a morbid sense of humor. But I would suggest to you that when basic principles that you can find in any textbook are routinely ignored in the political debate, it isn't economics that is the dismal science. It is political science that is the dismal science. And I hope we can shed a little sunshine on it before it gets really bad. Thank you.

A Canadian Economist's Perspective

By John R. Graham[7]

It's a pleasure and privilege to be here. I've done a lot of speaking in the U.S. on this issue because it's an issue of such concern. I hope I can keep everyone's attention. The Blue Jays actually won the World Series a few years ago, but I guess those days are long gone. So this is the best Canadian entertainment you get nowadays.

The Fraser Institute is a nonprofit charitable organization that does economic and social research on competitive markets and government intervention. We are broadly similar to The Heartland Institute, I believe, in our approach. This issue, which we call exportation to the American market, poses a threat to Canadians, as Professor Entin described. That's one reason we started looking at it.

I think we have a relatively elite audience here, which in a way is unfortunate. I'm glad we've got some media here too. But I'd like to shape my remarks such that they will reach the ears and influence the thoughts of ordinary Americans and residents of Illinois.

The problem here is politicians face terrible incentives when regulating the prescription drug market. Many of you will know that politicians have had negative consequences on the rest of the American health care system, and now they've set their eyes on prescription drugs and threaten to screw that up, too.

I remember a couple of years ago I was trying to understand the idea of term limits, because we don't have that in Canada, and it was explained to me. And I said, that's all wrong. You don't need a term limit; you need term *minimums*. Someone who is elected should have to serve for 30 or 40 years so he suffers the consequences of his actions.

In any democracy with an aging population, the easy political money to coin is to go after the votes of seniors. Reducing prescription costs is one

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obvious tactic, and you will not see the long-term, negative impact on innovation for 15 or 20 years. So the astute politician really can get away with it. So this message has to go to ordinary people so they can discipline their politicians and hold them accountable, so that stunts like reimportation are not put forward as a real solution to an important public policy problem.

Importation is not as big an issue in Canada as it is in the United States, but it is becoming a bigger issue because at least five major pharmaceutical manufacturers have said they will stop supplying the Internet pharmacies that are shipping drugs across the border to the United States. One provincial government in Canada, Manitoba, has the cockeyed notion that it is an effective industrial policy to have warehouses that ship prescription drugs to the United States. Manitoba has decided this is an export industry, not realizing it is an industry that is not sustainable, as Professor Entin alluded to and as I will describe a little bit later in my presentation.

Other Canadian provinces and the federal government so far are agnostic; they haven't quite thought their way through this. One of the reasons I wrote a paper on this subject[8] was to give some suggestions to the Canadian and other provincial governments as to how they should approach this threat to the Canadian drug supply.

Need a Focused Solution

I understand that many Americans are angry about high prescription drug prices, but let's not forget that the average American senior spends more on alcohol, tobacco, and entertainment than on prescription drugs. The number of people who are making the trade-off between buying groceries, paying the rent, and filling their prescriptions is very small.

Recently published research from the Medicare Current Beneficiary Survey from 1996 to 1999 found that less than 3 percent of the beneficiaries in that survey did not get the medicines prescribed to them. And of that 3 percent, not all who chose not to fill their prescriptions did so because of a financial burden. So you do have a small number of people who are really struggling, and you have to focus a solution on that small number.

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[8] *Prescription Drug Prices in Canada and the United States – Part 4: Canadian Prescriptions for American Patients Are Not the Solution* (Public Policy Source No. 70) Vancouver, BC: The Fraser Institute, September 2003.

One thing I want to bring up that hasn't been addressed by other speakers is why price differences exist between Canada and the United States, and between the United States and other countries. One element that has been mentioned is regulation. Every country has significant government intervention in their prescription drug market, and it looks different in different countries, but those interventions obviously affect prices. For example, in Canada, it takes 39 weeks longer at the median to approve new prescription drugs. So the new whiz-bang drugs that are getting approved in the United States just aren't available for sale in Canada.

Another reason Canadians spend less on drugs is that Canadians are poorer than you are in the United States. And when you look across borders, countries that have higher incomes tend to pay higher prices for pretty much everything than countries with lower incomes. That's not true for many commodities; gold and oil, for example, are the same price everywhere in the world. But as you go down the chain to more developed, differentiated products, you see significant price differences.

The American worker is about one-third more productive than the Canadian worker. Over the years, the Canadian dollar has dropped in value, taking Canadian prices down too. Automobile manufacturers have a problem similar to the problem drug manufacturers have. There's currently a lawsuit, more than one lawsuit I think, in the United States where dealers are reimporting automobiles from Canada to the United States to take advantage of the retail price difference between Canada and the United States.

A couple of years ago I compared prices for a number of goods across the border. Quicken Basic financial software, which many of you probably have, was 70 percent more expensive in the United States. AOL monthly Internet service was 40 percent more expensive in the United States.

It is important to keep this in your mind as you're thinking this problem through because there's no significant difference in government regulations or intervention that influence the relative price of financial planning software or Internet service provision in Canada and the United States. This shows that even if you got rid of all the regulatory differences between Canada and the United States, you would still have significant price differences.

Trade Issues

Another element I want to touch on is free trade versus parallel trade. Now, I don't know the audience very well. Maybe none of you give a hoot about free trade as an idea, but I do. I think free trade is a very important idea. Reimportation has confused a lot of people, including many conservative Republicans and a host of Representatives. There's a congressman from Texas, Ron Paul, who's a really good guy but he's all wrong on the reimportation issue because he's confused reimportation with free trade.

Free trade relies on the voluntary cooperation of all parties. You cannot force a manufacturer to act in the long term against his own interests. Free trade means that Pfizer, an American company, can sell Viagra around the world. It means that GlaxoSmithKline, a British company, and Bayer, a German company, can team up to produce a competing product, Levitra, and sell it throughout the world. I just saw an advertisement last night on TV for Levitra. That's free trade.

Free trade means allowing companies to set their own prices and enter into voluntary, negotiated, enforceable agreements with wholesalers and pharmacies regarding the prices they may charge for the product. Reimporting drugs renders these agreements unenforceable, thereby leading to a reduction in international trade because it gives manufacturers an incentive to reduce international engagements and investments.

As Professor Entin alluded to, we've got an $8 billion market, you've got a $155 billion market. The manufacturer's incentive is to make the problem go away by restricting supplies to the Canadian market. Domestically I recommended that our Canadian law should counter that threat by ensuring that the manufacturer, when he sends a drug to Canada for use by Canadian patients, the contracts that manage that distribution are enforceable under Canadian law. And that's what I'm trying to do back home, because the last thing we need is for the drug makers to make the problem go away by reducing their supplies to Canada.

There are also important implications of parallel trade for intellectual property. Patents are national laws. Pretty much every drug has a different patent term in Canada than the United States. Sometimes the patent in the United States expires earlier than the patent in Canada, and sometimes the patent in Canada expires earlier than the patent in the United States.

When Mrs. Clinton was running for the Senate in her 2000 campaign, she had a list of prescription drugs that were significantly cheaper in Canada versus the United States. One of those drugs was tamoxifen, which

at the time was patented in the United States. I believe the patent just expired a few months ago in the United States. But it has long been off patent in Canada.

By advocating that Americans buy Canadian tamoxifen, she was by implication saying that the U.S. patent—I believe Nolvadex is the brand name—was invalid. I doubt she had thought that through, since it implies that U.S. patent law should always be subordinated to patents in other countries that offer weaker protection, or protection for shorter periods of time. Because some countries are notoriously lax in defending patents, she should have come out and said we shouldn't have patents on prescription drugs at all.

Without patents, as Professor Entin has said, it is unlikely the U.S. would have the level of investment in research and development required to address people's needs in the future for new prescription drugs. So when you say you favor reimportation, you are saying in effect that you do not like U.S. patents. If that's your issue, then you should come out and address that issue directly instead of coming at it through the back door.

Safety Implications

In terms of safety, drug manufacturers have strong incentives to play a significant role in preventing counterfeiting, other types of fraud, and activities that threaten the integrity of the distribution chain that connects their factories to their customers. But they only have that incentive if you allow them to manage the distribution chain and to keep the markets differentiated.

If you tell manufacturers it is against the law for them to have input into the distribution chain, and it is against the law for them to profit from managing the distribution chain, then the manufacturer loses all interest, or a significant amount of his interest, in combating the counterfeiting problem.

The amount of government intervention that would be required to substitute for the manufacturer's interest in managing this risk would be huge, as would be the cost to consumers or taxpayers. There is simply no way to inspect every pill that comes across the border. To a large degree, as I understand it, the testing involves the destruction of the medicine, so the medicine you test is not available to consumers. Counterfeiters know how to salt their lots so if there's a sample, the sample will go through. There are

a lot of issues here that you really cannot manage without an immeasurably high level of government intervention, once you remove the manufacturer's incentive.

As a reminder, just to make clear, Health Canada has quite clearly said it has no role to play in the safety of these parallel traded drugs. The *Washington Post* has reported this, and published a letter from Health Canada on May 1 in which Health Canada officials affirmed they would not and could not ensure the quality of drugs exported to the U.S. So it is definitely a gray market in Canada and a black market in the United States, since it is explicitly illegal in the United States.

Regulation and R&D

The alternative to importing cheaper drugs from other countries into the U.S. is to lower the cost of producing and selling drugs here. I sometimes say the U.S. government, not drug companies, must stop gouging patients. As the state senator mentioned earlier, there's a lot of clinical testing required by legitimate manufacturers that may be overkill. I believe I quote Senator Rauschenberger correctly when he said, "We make the manufacturers spend hundreds of millions of dollars." So as citizens you've got to think of that and what your legislators are doing.

There's only one business in the world where the length of the patent is a real issue, and it's the pharmaceutical business. Other businesses have patents, but they don't really worry about whether it's 20 years or 20 years and six months because after three or four or five years, it's been out-innovated, so the patent on that product becomes irrelevant. It's been invented around. One reason that doesn't happen in the pharmaceutical industry is because of very heavy FDA regulation. We've got to speed up the innovation, speed up the R&D, which demands a regulatory response from the FDA.

If you look at the past four decades, the proportion of sales allocated to R&D in the brand name pharmaceutical industry has gone up from 10 percent in the 1960s to 18.2 percent in 2002. How much they spend on marketing and advertising—something critics often bring up—is a red herring, because there's a positive relationship with the amount spent on promotion in America and advertising and R&D. If you cannot sell your thing, you're not going to invest in R&D to do it.

Tort reform would also help lower drug costs here in the U.S. A paper

written by Richard Manning, then a professor at Brigham Young University, published in 1997,[9] argued from the evidence that one-third of the prescription drug price difference between Canada and the U.S. was the more burdensome litigation situation in the United States. The data he was using was from 1992. So whether that one-third difference still holds 11 years later, I don't know, but it would still hold to some degree.

Also, you've got to have more price differentiation *within* the United States. If it cost 20 cents to manufacture a drug, and you're selling it for a dollar, and there's somebody who cannot pay for it at a dollar, but he can pay 30 cents, the manufacturer has an interest in selling it to him for 30 cents. But you have to give the manufacturer the ability to differentiate that customer from Donald Trump who can pay a dollar or more.

Every time the governor of Illinois, or another politician, looks at a low price that's given to a low-income person and says, "I want that price for all my constituents," he or she screws up the ability of the manufacturer to offer that low price to anyone, and consequently to meet the needs of truly needy patients. All manufacturers can do is cut off the needy patients and charge high prices to the rest of you.

[9] Richard L. Manning, "Products Liability and Prescription Drug Prices in Canada and the United States," *Journal of Law and Economics* 40 (April 1997), pages 203-243.

Don’t Just Stand There, Do Something!

By Senator Chris Lauzen[10]

As I came in this morning, I was warned that I was the only speaker on the program with the other point of view. So it’s not the most comfortable place to be. I certainly respect every panelist who spoke today.

I do worry, though, that other than the ideas that have been touched on by my colleague in the Senate, Steve Rauschenberger, I worry that what’s being defended here is the status quo. Do you remember the expression when you were young, “Don’t just stand there, do something”? Well, I’ve been hearing that a lot these days.

I work for 212,000 people in the Kane, Kendall, and Lasalle County area. It’s not only the title of my remarks, but the spirit behind my effort for the past two years to reduce the cost of health care in Illinois. I can’t solve the whole thing, but I’m trying to start with any component, and then do something about it.

I’ve served in the state senate for 12 years, and we all wring our hands, and we all talk a lot, and health care prices keep going up. I have served on the Appropriations Committee and the Revenue Committee, both ends of the dollars coming in and the dollars going out. And I watch how the government spends $53 billion, how we collect $53 billion and how we spend $53 billion of your money, and it makes me very sad. And I also appreciate the humor from my fellow speakers about the politicians. We are doing the best we can.

My background is Duke University with honors, a CPA in Illinois, Harvard Business School. I consider myself a pro-profit kind of guy. And the more profit, the better, as long as there’s a level playing field and there’s plenty of competition. On the way in this morning I went over some of the papers Joe Bast sent over to me, and they are just fascinating. I would encourage you to read these experts’ papers.

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[10] Senator Chris Lauzen has represented the 25th district of Illinois since 1993. A CPA and a Harvard MBA, he serves as minority spokesperson on the Committee on Revenue and cochairman of the bipartisan Legislative Audit Commission.

The Public Is Angry

What I might bring to the discussion this morning is that I face and listen to the people whose lives depend on the theories we're talking about today. The folks who I work for, number one, hate to pay their property taxes. That's the number one complaint I get in my office. But the other is that they don't understand why, on average, prescription medication costs twice as much in the United States as it does in Canada. That's the question.

I just got more of the answer this morning on why tamoxifen to treat breast cancer costs ten times more here than in Canada. I'm buying my ticket this morning to get on the train. The lady in front of me has been struggling with cancer for two years. She asked me that question, about why it costs ten times more. Now, that kind of price difference is wrong. I think every person in this room knows it's wrong. No matter how you peel away the economic theory, you know that it's wrong.

The horror stories are true. I field those calls everyday, from people choosing between eating and prescription medication, splitting their pills in half. I learned today—and I marked down a note because I need to think about it some more—that I guess our seniors are spending more drinking and getting entertained than they spend on their prescription medication. Some folks would be insulted by that.

But the bottom line, the message I bring today, is that the status quo is unacceptable. Don't just stand there; you've got to do something about it. It's not just older people who are talking to me about this; it's also doctors, because they hear from their patients everyday. Doctors are telling me, "Chris, you've got to do something."

Then there are the pharmacists. One of the federal bills that I read about apparently would cut out the pharmacists, and they're placed right in the middle. While spending on prescription medication went up 100 percent, in that same period of time, according to the Illinois Merchants Association, the pharmacists' margin is going down by 2 to 3 percent. So they're caught in the middle, and there's nothing they can do. They hear it everyday. They complain to me. I'm glad pharmacists were included in one of the federal bills.

Small businessowners are asking me, "What the heck are you going to do, Lauzen, about my health insurance costs going up double digits? It went up last year and then again this year." I got a letter the other day from one of the top 40 emergency heart specialist surgeons in this country. His premiums for malpractice went from $50,000 a couple of years ago to

$550,000. And now his answer is to withdraw his services either from Illinois or altogether from that field. And I think, what an enormous loss. Something has to be done.

IllinoisHealthAlliance.com

I have a group of folks who come from all walks of life who will help me do my work on a volunteer basis. One of those people started to do research, and we found an organization called United Health Alliance in Vermont. Dr. Beth Wennar was working on this same program, and we thought, well, we'll bring that knowledge to Illinois and try to apply it for the benefit of the people here. We've called it IllinoisHealthAlliance.com.

One of the things I wanted to make sure I'd mention is that I have no financial stake in that operation. Frankly, I was insulted when one of my colleagues asked, "Well, Chris, why are you working so hard on this? Do you have a financial stake in that?" It was interesting. I don't. But I note there are some folks who do have a lot of money at stake.

We do two things on the website. One is it's an information clearinghouse. There are a lot of good programs out there, and a lot of good programs the drug manufacturers have brought forward. Whether it's a Circuit Breaker, Senior Care, the Veterans Administration, Medicare/Medicaid, or drug manufacturers' discount cards, that's all on one side of the page. You can click on that name, and it takes you directly to the information where you can participate.

I agree with the expert from Canada who says we have to do something about those folks who can't afford drugs at U.S. prices, and with our website we can help them find help. If they didn't qualify—and there are so many people who don't qualify for these subsidy programs—then we expedite the ordering process through Canada. The point is to drive down the cost of prescriptions by shining a light on the disparity, pull down the barriers, encourage competition, but one way or the other, get going on that process.

Drug Manufacturers Aren't Helping

I am not here today to pound on any drug manufacturers. The last time I was sick, I was very grateful that medication was available. But on the other hand, I'm not here to get taken advantage of by them either, and neither are

the 212,000 people whom I serve. Also, I regret that we have to send even one penny to Canada. No offense to anybody in that country! But if that's the lever it takes to get treated fairly, then I'd say, Mr. Gorbachev, tear down that wall of protectionism or perhaps the manipulation of the market that's going on right now between the United States and Canada.

Here's my experience with the drug manufacturers' reaction to just those who try to reduce the costs of the medications they're now paying. First of all, they try to confuse us. They say it's illegal. Well, I'm under the impression that if it's for personal use, no controlled substance, prescription acceptable to my pharmacist and also the Canadian pharmacist, then it's legal. But let's concede that point and let's look at the thousands of people everyday who go across the border in busloads or through the Internet.

And I say that a law that's not enforced is not a law. If you enforce it, people would say to me, "If you enforce it, Chris, we'll fire you. And we'll get somebody who's going to represent us more aggressively and solve these problems, and get about the business of the solution."

The second step is, if they can't confuse us, they scare us ... scare the heck out of us. "It's not safe!" The stories in the U.S. we've heard. The folks from the governor's delegation just got back. They say the system in place in Canada is very similar, if not more thorough, than our own systems for taking care of quality. The premise of that argument is that people in Canada, human beings in Canada, are different from human beings in the United States, that somehow they're less concerned about safety than we are. They're not, of course, and so of course they have in place rules and regulations that are similar to our own. None of us in whatever country wants to put poisons into our body.

And then there is the fact that many of these drugs are manufactured in the United States. They go in a big box. They go over to the Canadian pharmacy. One of the sealed containers gets put in a package and then sent back into the United States. And people say, well, if there's a problem in that originally sealed bottle, are you really saying we ought to take a harder look at how we manufacture prescription medications here in Illinois or in the United States?

The third thing I see as a reaction, after they feel they can't confuse us or scare us, is: "Cut them off." I went over to take a look at GlaxoSmithKline's audited financial statement. Frankly, I called the person who runs their organization in the United States. Here is a Great Britain company that uses the free-market, global economy rules to come to the

United States, derive most of its revenue and profit using those rules. But if a little old lady from Aurora, Illinois or Peoria, Illinois wants to use those same free-market, global economy rules to buy her prescription medication to keep herself alive—goes to Canada, in other words—these folks want to cut them off. Now, I have to tell you, that makes people angry.

Now, when I take a look as a CPA and a Harvard MBA at this financial statement, and I look at the research and development line on this, I find the selling, general and administrative line, is two-and-a-half to three times larger. Thirteen percent of their $30 billion of revenue goes into research and development. They spend two and a half to three times more in selling, general and administrative expense. They also bring two, two-and-a-half times as much to the bottom line. Before I ran for the Senate, I took care of 200 small businesses and reviewed each of their financial statements every month, and I never saw profit margins like that. This illustrates there's something wrong with the market; there's something wrong with the level of competition to have that outcome.

Let me summarize my concerns. There's a lot of money on the table here, and I understand that. The people who we all serve, either as customers or constituents, are actually angry. The objective is not to vilify drug manufacturers; that's not what we're here to do. But we are here to ask them to sell their drugs to us, their fellow U.S. citizens, for what they are selling to Canadian citizens. We just don't want to pay twice as much as our neighbors. Folks are insisting, don't just stand there, do something!

Costs, Compulsory Licensing, and Counterfeiting

By Grace-Marie Turner[11]

I agree with several points Senator Lauzen made earlier. People are angry about this issue, and they really do see it as an issue of costs. But prescription drug prices are just the tip of the iceberg of overall health spending increases. Focusing on drug prices alone is unlikely to solve the bigger problem.

The U.S. spent $1.5 trillion on health care last year. About one-tenth of that went to purchase prescription medications. Spending on prescription drugs is often more visible to consumers than spending on other health services, and as a result, that is the piece of overall health spending that people often focus on.

Senator Lauzen mentioned high health insurance costs which some people feel are out of control. In a lot of ways, the prescription drug issue stands for the public's anger at high overall health costs. Focusing on this one piece is a way of getting our arms around something that is much, much more complex.

I also think it might be important to walk you through where the issue of drug importation is from a legal perspective—because it is actually illegal to purchase drugs from foreign countries for anything other than personal use—and what is happening in Congress to try to change the legislation.

History of the Legislative Debate

Last summer, at the end of June, Congress was debating a big Medicare bill. Both the House and Senate bills contained provisions addressing drug importation, along with many other things, including spending $400 billion

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of taxpayer money over the next ten years to provide a Medicare prescription drug benefit and to fix a lot of the other problems in the Medicare program. It's a very big package. Drug importation was just one small part. The original language in both the House and Senate bills would allow importation of drugs from Canada provided the Secretary of Health and Human Services could certify both safety and savings.

The $400 billion Medicare bill passed the Senate by a vote of 76 to 21. But, it only passed the House by one vote, 216 to 215. And the leadership of the House had to keep that vote open until the middle of the night, just before people were ready to leave for their 4th of July recess, trying to get the last one vote to pass the bill.

Finally, Congresswoman Joanne Emerson, a Republican from Missouri, said she would vote for the bill if a vote were also allowed later on a bill proposed by Representative Gil Gutknecht, also a Republican, to allow importation of drugs from not just Canada, but from 25 other countries as well, almost all of which impose price controls on prescription drugs. The House leaders really wanted her vote, so they said yes to the deal.

Gutknecht's bill then did get its final up or down vote just before Congress left for its August recess. His bill basically would give the U.S. Food and Drug Administration a lot less authority to regulate the supply of drugs coming into this country from 26 countries.

And how do they pick those 26 countries? The bill says that if any facility in a country is approved by the FDA to do clinical trials, even if only in a closed university setting, then U.S. citizens, dealers, and wholesalers can import drugs from those counties. There is a real mismatch, I think, between whether or not facilities manufacturing prescription drugs are safe and up to FDA standards and whether the FDA can control the quality of drugs used in limited clinical testing environments. The latter is comparatively much easier than the former.

Still, the Gutknecht bill passed the House. It now has been sent over to the Medicare conference committee that is trying to reconcile the significant differences between the House and Senate Medicare bills. The conference committee is right now deciding how we are going to address this issue. Because it's so emotional, it's hard for people to understand some of the other issues going on.

The Reason for Price Differences

How did we get into this position? I think concerns about high drug costs and a negative view of the pharmaceutical industry have collided, at the same time Americans have grown increasingly angry over paying what they perceive to be a disproportionate share of the research cost for prescription drugs. I think that was really the thing that turned the corner in the House vote, because members realized that American consumers are paying a disproportionate share of R&D costs, that the French and the Germans and the English are not paying their fair share. And they got mad about it, and they essentially took out this sledgehammer and said, "Bam!" to the pharmaceutical industry, "Fix this. We don't like this."

Why, then, does the pharmaceutical industry sell drugs to the French and the Germans so far below U.S. prices, at least in some cases? Why do we have to be the ones who pay for so much of these research and development costs? The answer is something called compulsory licensing. It's a law that these countries have on their books that says if the government can't reach an agreement with drug companies over a price the government is willing to pay, the government can say the drug companies are not making their products available in the country, and can license a different company to make and sell the drug.

Either drug companies negotiate a deal in which they can make a little bit of profit so they can at least cover their manufacturing cost, or they stand to lose the thing that's of most value to them, and that's their intellectual property rights. That's why the companies make the deal. These countries are using their government-run health care systems to essentially strong-arm companies to sell at below-market rates. Because other countries demand below-market prices, Americans are paying higher prices.

Real Safety Risks

Congressman Gutknecht was quoted by the *New York Times* recently, saying, "The FDA's blind refutation of fact and its duplicity in making safety claims are predictable and pathetic." And what does the FDA say about this? FDA Commissioner Mark McClellan says he believes this legislation to allow imports from 26 countries creates "a wide channel for large volumes of unapproved drugs and other products to enter the United States that are potentially injurious to public health and pose a threat to the security of our nation's drug supply."

The White House issued a statement saying essentially the same thing. But, interestingly, this is not a partisan issue. Congressman John Dingell, a Democrat from Michigan and a leader on health policy in Congress, said he thinks the Gutknecht bill will allow this country to be "flooded with unsafe, counterfeit drugs, drugs that will not do what they should, drugs that are unsafe and drugs that will kill the American people."

Governor McGreevey of New Jersey, also a Democrat, made a similar statement, saying, "Re-importation is not a substitute for a comprehensive drug benefit program. Congress on a bipartisan basis must pass a Medicare drug benefit plan and New Jersey is asking for the adoption of a drug benefit." And I understand Mayor Daley of Chicago is also very much against importation both for safety issues and also because he doesn't believe the idea will do what it's supposed to do.

Do you remember the Tylenol scare in 1982? Somebody, some deranged person, went to a drug store and bought a dozen, two dozen—nobody knows for sure—bottles of Tylenol off the shelf, laced the pills with cyanide, and put them back where unsuspecting people bought them. Seven people died before authorities were able to figure out what was going on.

Immediately afterward, every bottle of Tylenol was pulled from every shelf in every drug store in America. And then every drug company in the U.S.—not just Johnson & Johnson that makes Tylenol—figured out how to make tamper-proof packaging so consumers could tell if that package had been opened. Over-the-counter medicines have been made and packaged since then in such a way that they are much more difficult to tamper with.

The Tylenol scare demonstrates how vulnerable our nation's drug supply is to terrorists and counterfeiters. The Gutknecht bill essentially says companies must put anti-counterfeiting and anti-tampering markings on every drug they make around the world to keep that from happening. It is possible for pharmaceutical companies to keep careful tabs on medicines made in manufacturing plants that they own or contract with in other countries. For example, there are plants in Ireland where drugs are manufactured under very controlled conditions, which the FDA carefully monitors. The drugs are tracked through the supply chain as they are shipped to U.S. distributors who are expected to also keep a paper trail for the drugs.

But this sort of security requires careful monitoring and control. If we open our borders to 26 other countries, shipping drugs over the Internet into

the United States, there is really no way the FDA could possibly monitor all those shipments to see if they are safe and to make sure people are getting the drugs they believe they are buying. And what is to keep people from operating drug manufacturing plants that are completely outside the scrutiny of the FDA or the control of the pharmaceutical companies and then slipping those drugs into the distribution system?

The Gutknecht bill would, as a recent *Washington Post* series says, enable "pharmaceutical peddlers [to] take advantage of lax regulations to move millions of prescription drugs into the United States from Canada, Mexico, and elsewhere. Overwhelmed customs workers inspect less than 1 percent in an estimated two million packages containing medicine shipped into the country each year."

And who is to stop someone from using the Internet to perpetuate another Tylenol scare on Americans? We saw from the anthrax scare that it takes only four or five letters to scare all of us, to nearly shut down the U.S. mail service for several months. The same thing is true with prescription drugs. Drugs are not going to come just from FDA-monitored facilities like the one in Ireland, but it will open our borders to the bad players the *Washington Post* series described.

Buyer Beware?

The warning "buyer beware" doesn't work very well to protect consumers from counterfeit or adulterated drugs. How can someone know if the drug they purchased over the Internet caused the adverse reactions they experienced? How can we tell if a patient's death was due to the illness or because the drug dosage was only 1/20th of what it should have been? Counterfeit drugs can look remarkably like the real thing but contain too much, too little, or none of the active ingredient the medicine is supposed to have.

The threat to health and safety is very real. Take the example of a diabetic taking insulin who decides to try to save some money and buy insulin over the Internet from Canada, which actually happened. But the patient was getting sicker and sicker and went back to the doctor six or seven times because he was just not able to get the dosage right, only to find out that the "insulin" was sugar water.

Counterfeiting drugs is often more profitable than counterfeiting currency these days, and in some ways easier, because there are up to 20

layers of anti-counterfeiting technologies in currency. The battle against currency counterfeiters is instructive, by the way. The government continues to have to keep ahead of counterfeiters because they do figure out the technologies. They do the same thing with anti-counterfeiting technologies for drugs.

Do we really want to multiply the security threat to the U.S. drug supply? The FDA has its hands full protecting our domestic drug supply even without opening the border to 26 other countries, including countries we know harbor people who want to do harm to the citizens of the United States.

So, there are the risks, and yes, there are bad actors out there, in other countries as well as in the United States—people who just want to make a buck and don't care at all about public safety. The FDA needs to spend its time protecting us from these people. Opening our borders to drugs from Namibia and Bangladesh and Iran and Saudi Arabia—as would likely happen—would make the FDA's job infinitely more difficult, maybe impossible.

The safety and security of our drug supply to assure people that the drugs they are taking are the drugs they need—that is what is at stake in the debate over drug importation.

It's Really About Spending, Not Safety

By Sean Heather[12]

The U.S. Chamber of Commerce is opposed to drug importation. However, I understand the position Governor Blagojevich is in. I understand the position that an 85-year-old woman or man is in, who depends on prescription drugs and needs access to affordable drugs, because my members have problems providing drug coverage to their employees. They have problems, for that matter, providing health care of any kind to their employees.

So, I consider myself to be in the same boat as those folks who are trying to lower the costs of health care. I would suggest that we could change the name of this forum to the "National Symposium on Health Care Cost Control." This week we're talking about prescription drugs. Next week we might be talking about medical malpractice. The week after we might be talking about association health plans.

The Real Issue

The underlying problem is health care costs are skyrocketing in America. I was asked to speak about safety, but I'm going to tell you, safety is a red herring in this argument. Safety is a legitimate concern, but it is not the issue that is actually driving the drug importation debate.

I challenge Congress to stand up and instead of passing an importation bill, as they did with the Gutknecht legislation, to vote on whether we, as a country, should have price controls. They did not do that. And my question to all members of Congress who supported the Gutknecht legislation, regardless of party, is why are you trying to get price controls in the United States through the back door? Why not have the courage to

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stand up and have an honest debate about whether or not price controls are the right approach?

We as a nation have a real problem when it comes to health care. We decided long ago that health care is an entitlement. You and I and everyone in this room are entitled to health care. If you are part of Medicare or Medicaid, you get health care. If you're uninsured, every nonprofit hospital in the state of Illinois and every other state in the union is required by law to provide health care. If you're not in one of those two categories that means you're covered by insurance. Most of that insurance comes from your employer.

So at the end of the day, everybody is entitled to health care. The decision we are struggling with today is *how much* health care you are entitled to. Today we're talking about prescription drugs and managing the cost associated with that, but we could just as easily be talking about reducing medical malpractice lawsuits or allowing association health plans, or enabling small businesses to pool their risks and get access to affordable health insurance the way bigger companies do because they're able to self-insure.

It's difficult for companies to grow and expand when they cannot use dollars and resources toward capital improvement and expansion and have to put it towards the cost of health care instead. There's plenty of anecdotal evidence as well as statistical evidence that would show that rising health care costs are hurting U.S. companies. Each company has only so many dollars and they can do only so many things with those dollars. They can either put it towards the human and physical capital they need to remain competitive with competitors in other countries, and to continue to innovate and meet consumers' needs, or they have to spend it on the ever-rising cost of health care for their employees and retirees. It's a choice employers have to make every single day.

Drug importation doesn't solve this problem for employers. We're just working around the margins of the problem because we have not answered this question: how much health care are we entitled to?

The Safety Issue

My economics professor—I started an MBA program about a month ago—would say less safety is the unintended consequence associated with this well-intended legislation. The intention is not to create a safety

problem, but to help control health care costs. Safety is a legitimate issue, and those people who've suggested that we could design a program that would eliminate the hazards associated with bringing in counterfeit drugs should be required to prove they can do it. The INS can't police our borders to keep illegal immigrants out of the United States. The FDA, which was not designed to do that, is now going to have to patrol our borders to keep out dangerous drugs? Do you think they're going to be effective at that? You're fooling yourself if you do.

Counterfeiting isn't unique to drugs, of course, but it may be uniquely dangerous. Consider Major League Baseball, for example. You can get a jersey for a player with the Chicago Cubs, and there should be a tag on it that says "licensed by Major League Baseball" with a little fancy hologram. Now, if you sit down with the intellectual property attorneys for Major League Baseball, they will tell you that counterfeit jerseys are coming by the thousands from China and aren't licensed by Major League Baseball.

Now, when somebody buys that jersey, is anybody harmed? The companies that are paying big fees for the license may be, but not consumers. The jersey probably looks the same, feels the same, they can wear it to the Cubs game, they're not any less of a Cubs fan because they have it. But things are a lot different when you're talking about lifesaving medication. The consequences of buying a fake are much, much worse for the consumer, possibly fatal. And often, nobody, even an expert, can tell the difference between a "real" pill and a fake one without conducting sophisticated tests. So it's easy to counterfeit drugs, and the consequences are worse than in other cases.

What happens when a dangerous fake drug gets through? Somebody's going to sue. They're not going to be able to sue the federal government or the state of Illinois, so they're going to want to sue the drug manufacturer who had nothing to do with the injury. Litigation is one of the reasons why importation would be difficult to do in a cost-effective manner. When the process goes wrong and a consumer dies, we are a nation that wants to point the finger at somebody and say somebody's accountable and has to pay. I've never seen the federal government pay out a $1 billion settlement to anybody or the state of Illinois pay out a $1 billion settlement. When they write legislation, they carve themselves out a liability exemption. It's the private sector that ends up paying.

But let's say the advocates of importation can design a counterfeit-proof importation system. The cost associated with designing that system would

probably remove the entire amount of money we would be saving by importation. So, savings become a mute point. Even if we dedicate the amount of resources needed to get the job done, economically we can't solve the equation, because we'll spend more money trying to assure that the drug you get from Canada—that may have been imported from Iran to Canada and then passed through to the United States—is more than the difference in price between Canadian and U.S. drugs.

Price Controls

Do we want to put price controls on this marketplace? Historically, we've been a capitalist society. Pharmaceuticals are traded on the stock exchange. We all own mutual funds. Every mutual fund out there, I am sure, has a percentage of it invested in Advit, Pfizer, Merck, you go on down the line.

We have a real decision to make here: whether or not we want to, for the first time in a very severe way, inhibit the capitalist system. No one has mentioned that last week, *Business Week* ran an interesting article on this subject. *Business Week*'s reporters went to Europe and talked to some of the European commissioners and guess what? Europe is deciding, as we speak, to go back to a market-based system!

Why is that? Because, in the 20 years or so since they put price caps in place, they have watched the pharmaceutical industry in Europe dry up. About 20 years ago, a third of the pharmaceutical industry was based in Europe, a third in the United States, and a third elsewhere. Now, 50 percent of the pharmaceutical research that goes on is done in the United States, and we reap the jobs associated with that. The Europeans have seen the economic impact of that and don't want to be where they are currently at.

Price controls are bad. Governments here in the U.S. should be working to end price controls in Europe, eliminate price controls in Canada, instead of adopting their system and methodology here in the U.S.

Conclusion

The issue of whether you're entitled to health care, I think, has been settled. But the issue of *how much* you are entitled to is of the greatest interest to the U.S. Chamber of Commerce, because my members are stuck in the middle. My employers are trying to find a way to provide health care to their employees because they want to do the right thing.

We recognize that today the most effective medicine is often delivered in the form of a pill rather than through hospitals and surgery. We've discovered that you can save money in the long run by encouraging the use of prescription drugs to prevent the much more painful and costly consequences of illnesses going untreated. So, it is in our interest to be significantly engaged in this debate.

The system needs reform, but importation is the wrong way to do it. The problem isn't safety—safety is a red herring—it's cost. Importation isn't the way to control costs. It's just a way to import price controls in the U.S., and the threat to our safety is an unintended consequence of that flawed approach.

Members of Congress decided to vote for importation, not because they were interested in or worried about safety. They were interested in and worrying about controlling costs. I encourage them to stand up and start the debate about whether or not we should impose price controls on this industry. The U.S. Chamber would not be in favor of such a thing, but that is where the debate should be and not, I think, over whether and how we can safely import drugs from Canada.

The Pros and Cons of Drug Importation

By Joseph L. Bast[13]

The speakers at this conference gave us a good idea of the depth of this issue. It is not simple. Over the course of the day, I heard seven good reasons why we should import drugs from Canada, and eight good reasons why we should not. I will try to summarize these arguments as briefly as possible. The seven arguments for importation are:

(1) Many people are paying too much for their prescription drugs or can't afford to buy them at all. The state of Illinois can't afford the 10 percent and 12 percent annual increases in the amount they are spending on drugs. We know that drugs in Canada are cheaper, so it's an obvious opportunity to cut costs and possibly, for some of these people, save lives.

(2) Canadian drugs are safe. Critics cannot point to people who have died from drugs that were imported from Canada. They say, "well, wait until the next news cycle and we may be quite shocked to learn otherwise," but that hasn't happened yet. Right now, a strong case can be made that current importation is safe.

(3) Consumers should be free to buy a legal product from a willing seller. As a libertarian myself, I think that should be true in a wide array of areas. Why should we make an exception in this case?

(4) International trade is a source of tremendous consumer benefit. Any argument for trade restrictions has to overcome the strong presumption in favor of free trade. How is this product so different from nearly all other products that it justifies a ban on international trade?

(5) There is nothing in the U.S. Constitution that says the federal

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government should protect me from Canadian drugs. If it's not in the Constitution, it's not within the power of the federal government to do it. It should be delegated to state and local governments. They should be able to make their own choices on this issue.

(6) Companies that want to place restrictions on the price at which they sell their products to other countries ought to be required to enforce those contracts themselves. Why is the government doing their dirty work for them? Sen. Chris Lauzen pointed out what he thought were excessive profits on the part of prescription drug companies, which he thought indicated there was a lack of competition in this market. If that's true, what we've got now is not really a free market.

(7) Sen. Lauzen and some of our audience members said repeatedly that price discrimination is simply unfair. Lauzen said it is wrong that some people are being charged twice or three times as much as other people, that people are right to be angry about it, and that elected officials are being called on to do something about it.

I also heard eight reasons why importation is a bad idea:

(1) Consumer safety trumps consumer choice in this case. Why? Because, "let the buyer beware" doesn't work when you're dealing with prescription drugs. Even an expert can't distinguish a safe and effective pill from a counterfeit, substitute, contaminated, or expired pill. And once they have entered the country, tracking and removing these poisons would be extremely costly.

(2) Cheap imports mean drug companies are going to have to cut their prices, they're going to have less money to put into research and development. That would dry up the funds that make a very innovative, productive industry possible. The result would be lost jobs and fewer new lifesaving drugs.

(3) Price controls are inefficient. Throughout history governments have tried to put price controls on various products. It has never worked. It's led to distortions, evasions, black markets, waste, and inefficiency. The same thing will happen if we attempt to impose price controls on drugs.

(4) Importation is a stalking horse for something else. Drug importation is the first step toward greater government control over the prescription drug industry. Right now the government exercises massive control and interference in other parts of the health care system. The drug industry is probably the freest part of the health care industry. Importation would be the first step toward bringing the drug industry into the same kind of restrictions, regulations, and price controls that have made a mess out of the rest of the health industry.

(5) Importation violates intellectual property rights, patents in particular. Importation says that if a patent has expired or isn't honored in any country, it doesn't have to be honored in the United States. This vitiates any patent protection. Without strong patent protection, you will see less innovation and fewer lives saved by new drugs.

(6) Importation is not a long-term solution. Companies will simply export fewer drugs to Canada. Since Canada's market is very tiny compared to the U.S. market and since it imports most of the drugs it needs for its own residents, within a year or two the price differential would disappear, much to the disadvantage of Canadians, and we will have gained very little.

(7) There are alternatives. Right now, 5.5 million patients get free medicine from discount cards provided by major pharmaceutical manufacturers. All of the major drug companies have discount card programs that give drugs at very low price or even for free to people who are senior citizens and low-income. They also give substantial discounts to Medicaid programs and to state employees. It was mentioned briefly that state employees here in Illinois get substantial discounts already through the state program, so the difference in the price between Canadian drugs and the drugs they're already getting will probably be quite small.

(8) Litigation looms. If you work for the state of Illinois or are a retired state employee or if you're on Medicaid, under Governor Blagojevich's plan, you would be receiving drugs imported from Canada and not inspected by either Health Canada or the FDA. If one of those drugs is found to be counterfeit or contaminated or expired or in some other way a threat to your health, who do you hold accountable? Do you sue the guy who sold it to the state? Do you sue the state for allowing these drugs to be provided to you?

Do you sue the original manufacturer for failing to prevent the fraud? It becomes very confusing, and in confusing situations, I have noticed that lawyers make tons and tons of money and the victims typically get very little.

I hope that's a fairly evenhanded description of the pros and cons of drug importation. I would like very much to host this sort of debate again in three or four months. I hope that I'll see all of you here when we do this again. Thank you very much for attending and have a safe and pleasant trip back home.

Appendix 1

Blagojevich's $91 Million Mistake

By Joseph L. Bast[14]

In October 2003, Governor Rod Blagojevich and Congressman Rahm Emanuel announced the release of a government report claiming the State of Illinois could save $91 million a year by importing Canadian drugs for state employees and retirees. The figure appeared in newspapers across the nation, and the Governor repeated it as recently as November 25 in a letter to other governors urging them to follow Illinois' lead.

The number vastly overstates the likely savings. It is, in fact, contradicted by the report itself.

The Governor's report presents more than one estimate of the savings. The highest estimate, $91 million, assumes *every* state employee and retiree would order *all* the drugs they need (approved for importation) from Canada. The report's authors admit that simply won't happen. They say a 33 percent participation rate might be more realistic, reducing the savings to $30 million.

Even $30 million, though, is wrong. Importation would probably *increase*, rather than decrease, state spending on prescription drugs, because advocates of importation make five assumptions, all of them wrong.

Assumption #1: Drug companies would not reduce the discounts and rebates they give to the state's prescription benefit manager for drugs that would not be imported. The task force says only about half the brand drugs ordered by state employees and retirees can be safely imported from Canada. Drug companies would be tempted to raise prices on the remaining drugs to make up for lost revenue.

Assumption #2: There would be no increase in the price of drugs from Canada. The Canadian domestic market for prescription drugs is barely 5 percent the size of the U.S. market, and most drugs purchased by Canadians

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are imported. Six drug companies have already announced they will limit their sales of drugs to Canada to discourage reimportation. Higher demand and limited supplies has already caused prices to rise, and further price increases would eliminate whatever savings the Blagojevich team hopes to achieve.

Assumption #3: There would be no increase in security costs. The Governor's "special advocates" inspected a small number of Canadian pharmacies and drug factories and concluded they are as safe "or even safer" than U.S. facilities. But this avoids the real issue. Are regulations and enforcement efforts sufficient for a small closed market be able to cope with a market five or ten times as large, involving large-scale transshipment of drugs from other countries through Canada? Importation would also require expensive improvements in the U.S. drug security system.

Assumption #4: There would be no increase in utilization by state employees and retirees. According to the task force, individual employees and retirees would receive approximately one-third of the savings from importation. This fall in cost would prompt an increase in the volume of drugs ordered and substitution of brand drugs for less-expensive generics and over-the-counter drugs.

Assumption #5: There would be no reduction in the supplemental rebates drug companies voluntarily pay to the state's Department of Public Aid. According to the task force, drug companies today pay the State of Illinois $50 million a year to be allowed to sell their drugs to the state's Medicaid population. This subsidy to the state is voluntarily negotiated and made possible by profits generated from selling drugs at higher prices to other customers. Importation would pose an obvious threat to this system, once again potentially cancelling out any savings.

All five of these assumptions are probably wrong. If any *one* of them is wrong, importing drugs from Canada would be unlikely to save taxpayers any money. If two or more of these assumptions are wrong, taxpayers could end up paying more ... for second-best drugs.

Do Congressman Emanuel and Governor Blagojevich fail to see the faults of importation? Or are they pandering to the general public, which opinion polls show supports drug importation by a wide margin but does not understand the costs and consequences?

Perhaps the congressman and governor should find some other issue to politicize, one less likely to pose a threat to the health and safety of the state's employees and retirees.

Appendix 2

Letter from the FDA to the State of Illinois

November 6, 2003

Ram Kamath
Scott McKibbon
Special Advocates for Prescription Drugs
100 W. Randolph Street, Floor 4, Suite 457
Chicago, Illinois 60601

Dear Dr. Kamath and Mr. McKibbon:

I write to respond to the report that you presented last week to Governor Blagojevich on the feasibility of purchasing prescription drugs from Canada. Let me say at the outset that we here at the Food and Drug Administration fully understand and appreciate the concerns Governor Blagojevich has about the need for assisting Illinois citizens who cannot afford their prescription medications, and the need for addressing the rising prescription drug costs being borne by state and local governments.

Public officials across the country, at all levels of government, are struggling to find answers to these problems. We believe that further actions are needed to reduce prescription drug costs without creating new safety risks for patients, especially at a time when the potential threats to drug safety from counterfeit drugs, unapproved drugs, and drugs that are improperly dispensed and used are greater than ever.

As FDA Commissioner Mark McClellan has repeatedly stated, Americans deserve access to drugs that are safe, effective and affordable. And the FDA is doing something about it. Earlier this year, we accelerated the process that brings generic drugs on the market, reducing overall health care costs over the next ten years by an estimated $35 billion.

In addition, the agency is advancing several programs to lower the costs of both drug development and manufacture, and to help prevent costly

medical errors and drug-associated complications. And, of course, the Administration and Congress are closer than ever to enacting a prescription drug benefit as part of Medicare that will substantially increase access to affordable prescription drugs for seniors.

In 1987, in response to instances of unapproved and unsafe foreign medicines entering the United States, Congress enacted legislation to prohibit the importation of unapproved medicines. While the public health threats caused by such medications were significant enough for Congress to act in 1987, the potential threats from unapproved prescription drugs are even greater today.

Unapproved and unregulated medicines bought over the Internet can come from anywhere. Even medicines that appear to be the same or have the same brand name as those bought in the United States can be dangerously different. We cannot and must not allow the Internet to become the 21st Century's snake oil outlet.

Unregulated importation endangers the lives of America's seniors. Recently an 82-year-old man suffering from epilepsy and an enlarged prostate purchased what he was led to believe were FDA-approved drugs from a web site purportedly representing a Canadian pharmacy. Upon receipt, he noticed that they were from India. He called the FDA, and we determined that not only were the drugs not from Canada, but were, indeed, fake "knockoffs" of an American drug. "Buyer Beware" is bad health care practice and even worse health care policy.

In considering any proposal that affects the health of the public, it is important to consider the risks and benefits. On the "benefit" side, your report is misinterpreted to mean that importing drugs from Canada would be a smart bargain for Illinois employees and retirees, when this is far from the truth. Your estimate of maximum possible savings of more than 27 percent of drug spending greatly overstates the net savings the plan might achieve in practice. Indeed, this estimate appears to represent an implausible upper-boundary that inappropriately assumes "all eligible prescriptions are filled through the proposed Canadian Mail Order Plan."

In fact the report states "Based on current domestic mail order participation of approximately 7 percent of eligible prescriptions, we would estimate a participation rate of at least 33 percent given the extremely small proposed out-of-pocket cost to the participant." Thus the best guess of savings would be about 9 percent annually. And most of these hypothetical, limited savings would be for the government. According to your report's

own estimates, patients would receive only about a third of the savings. Even these small estimated savings substantially overstate the likely effect because important costs—pharmacist costs, shipping costs, liability costs, and others—are omitted.

Against these relatively modest savings are important health risks that are either misunderstood or ignored in your report. These risks indicate that there are far better ways to get savings in medical costs for Illinois residents than by turning to a questionable importation scheme.

On the "risk" side, the report fails to address the implications of buying drugs through the regulatory gap that exists at the border. Your report wrongly assumes regulatory oversight by Canadian health authorities of drugs exported to our citizens, when those authorities have not been willing or able to guarantee the safety of drugs sold to Americans. We understand that you did not include Health Canada in your fact-finding trip to Canada, nor otherwise sought assurances from Canadian health authorities that they would assure that drugs imported to Americans meet FDA's standards for drug quality, safety and purity.

Your report also assumes the safety of drugs that happen to be imported across the U.S.-Canadian border. While we have often noted that Canadian health authorities set high standards for drugs sold to their citizens, we have also consistently observed that drugs sold outside of the U.S. and Canadian systems (e.g., over the Internet) often do not meet such high standards. Indeed, we have seen concrete examples of drugs sold to Americans by Canadian Internet pharmacies that pose a risk to our citizens. (1)

We are also concerned that your plan, if implemented, would be in direct conflict with Federal and state law. As you know, prescription drugs sold in the United States must be approved by the FDA before they can enter the market, and drugs from foreign countries would generally not meet that requirement. I would leave it up to your pharmacy and legal experts to judge whether the program would violate current Illinois state pharmacy law, which parallels the Federal law, and also requires that drugs dispensed in Illinois be dispensed only by state-licensed pharmacies.

Drugs imported from Canada virtually never have the FDA-approved U.S. labeling, which is designed to inform patients about the drug's proper use and to give them warnings about particular dangers inherent in the drug. As a result, it is unclear how under this plan Illinois would ensure that its citizens get the necessary information and warnings.

Liability is another critical issue that the report fails adequately to

address. It is inconceivable to FDA scientists that there will not be some injuries arising from the sale of unapproved drugs to your employees or citizens. Selling such unregulated products will require substantially more liability insurance than is currently the case, unless Illinois consumers bear the risk of such injuries themselves. The costs of the additional insurance premiums are excluded from the cost estimates presented in the report. Given that wrongful death settlements are commonly millions of dollars, it is quite plausible that the net savings from the Illinois proposal, measured properly to net out the increased liability cost, would be significantly smaller than the 9 percent estimate mentioned earlier. Moreover, we query whether the state would be potentially liable in tort if a drug that the state purchased and sold in violation of Federal law injured an Illinois citizen.

FDA has not researched and does not advise you of any tort liability that will necessarily arise, but we urge that state officials consult with the appropriate legal advisors, as it is clear that the drugs purchased will be illegal and that safety concerns about them were discussed in our recent meeting with you. Finally, purchases of drugs from Canada will presumably be made over a disclaimer to the effect that the international "pharmacy" does not assure the safety of its products; such disclaimers are common among Canadian Internet pharmacies.

The history of drug regulation and legislation in the U.S. suggests it is detrimental to the health of Illinois citizens to be expected to obtain their medical care under such "buyer beware" conditions, but the report neglects the costs of making some other party liable. It does not appear that Illinois has or is developing any mechanism in place to evaluate adverse events occurring in their employees and retirees who use imported drugs.

Your program assumes that pharmacists in Illinois will participate in your primary care pharmacist model. Although pharmacy practices have become much more efficient in recent years, we are skeptical that pharmacists will participate in the plan unless they are adequately compensated both for "primary care" services and for the liability risks associated with providing unapproved drugs. Defraying these costs could easily consume all of the savings your plan claims that it will generate, and it might even cost more.

We also wish to point out that, in some areas, your report suggests limited knowledge of how pharmaceutical distribution practices actually work. This has implications for safety as well. For example, your plan states that drugs exported from Canadian pharmacies are shipped in "unit-of-use"

containers that would reduce both medication errors and the likelihood of counterfeit drugs—because pills are packaged as individual units in tamper-resistant packaging. However, our surveys of the actual drugs being mailed to Americans patients from Canada have found that very few are in true "unit-of-use" containers. Rather, the drugs tend to be more in the manufacturers' "stock" bottles, which tend to come in specific large volume amounts (e.g., 100 tablets). (2)

These bottles are not intended to be used by individual patients whose prescriptions are for more or less than 100 units; moreover, they do not generally include appropriate labeling and warnings for patients. Thus, medication errors can actually be encouraged, and many patients appear to be getting larger quantities than their doctors are prescribing. Further, although you are correct that true unit-of-use packages may help deter counterfeiters, such criminals have proven to be quite adept at accurately copying manufacturer stock bottles.

You also claim in your report that counterfeiting of drugs is less likely to occur in Canada than in the United States. But it is incorrect to imply that counterfeiting is not a real threat across the border. In fact, we have a number of counterfeiting cases under investigation with our colleagues at the Royal Canadian Mounted Police. Moreover, an importation plan such as this, with no reliable anti-counterfeiting measures included and with some fundamental misunderstandings of how drugs are distributed in Canada, could encourage counterfeiters to increasingly use Canada as an entry point for the U.S. market.

I would like to encourage your task force to consider a broader range of options for reducing the costs of safe and effective drugs. For example, although generic drugs comprise more than half of prescriptions filled in the U.S. today, many Americans do not realize that generic versions of brand name drugs are available and are much less expensive for treating their health problems. Generics in the U.S. are also generally cheaper—often much cheaper—than generic drugs in Canada. Many of the drugs on your approved list either have generic versions available or involve conditions for which much less expensive generic versions are available.

So I urge you to consider proven and safe sources of savings as you develop whatever program emerges for your citizens. And, as you may know, at the FDA we have taken many steps to speed the availability of more generic drugs, leading to billions of dollars in savings for patients, as well as to help doctors and patients get better information on the treatments

available to meet their medical needs.

And as soon as Congress acts, the purchasing power of a Medicare drug benefit will allow seniors who get little assistance with drug costs today to access drugs at much lower prices. And there are steps you can take as well. For example, well over 10 percent of the drugs on your list have generic or therapeutic equivalents versions available in the United States, which are just as safe and effective as brand name drugs but generally cost about 70 percent less, and are less expensive in the United States than in Canada. Encouraging the use of such drugs widely could achieve substantial savings, without compromising safety or quality at all.

We would add that there are other flaws in the report that suggest that even savings of 9 percent are significantly higher than what the plan will realize.

- Even the 33 percent participation rate that you preferred in the report may be too high because Canadian purchases would be limited to repeat prescriptions, and would require a detailed medical history for the patient. Some patients may elect not to participate because the twelve-dollar shipping costs may be higher than the patient's co-pay in some insurance plans.

- The estimated cost savings appear not to net out that $12 per shipment delivery cost. Correctly accounting for shipping costs would significantly lower the estimate of total cost savings.

- The report underestimates program implementation costs by about $2 million through an inadvertent math error.

- The report overstates cost savings by inappropriately comparing current spending on drugs by the State of Illinois, with spending on large packages intended to provide a long-term supply of drugs. This analytic approach artificially overstates savings because these larger packages are typically cheaper on a per day basis. The report also wrongly neglects the additional inconvenience and financial risk to consumers of buying drugs in 90 day supplies and then being unable to return them for cash or credit to mail order Canadian-based pharmacists if their prescriptions are changed for medical reasons.

In conclusion, I want to repeat that we agree with Governor Blagojevich that we must find better ways of ensuring access to affordable drugs for all Americans. But we must not compromise safety in the process. Your proposal for "buyer beware" drugs simply doesn't achieve the key goals of affordability and safety. Importing unregulated foreign drugs will not accomplish those dual goals.

Compromising safety for price is not in the best interest of the American public, and we should not force Americans to settle for that. We at the FDA are working diligently to help find solutions that do not force Americans to choose between medicines that are safe, and medicines that are affordable. Finally, the U.S. public health system should not be undermined by schemes that put those most in need most directly at risk.

Sincerely,

William K. Hubbard
Associate Commissioner for Policy & Planning

Notes:

1 Just recently FDA surveyed drugs being imported through four mail facilities, which revealed serious safety concerns about a number of Canadian imports. For example, FDA found that taro-warfarin, an apparently unapproved version of warfarin, was being shipped to U.S. patients. FDA-approved warfarin is used to prevent blood clotting, and its potency may vary depending on how it is manufactured. Life-threatening bleeding may result if the patient doesn't get the proper drug with proper monitoring during treatment. The taro-warfarin being sent from Canada was apparently not the FDA-approved version and could thus potentially pose serious safety risks. Other similar examples were found in the surveys.

2 Our colleagues at the Consumer Product Safety Commission, which oversees the child resistant packaging laws to protect children from accidental drug poisoning, inform us that these "stock bottles" that are so commonly sent to U.S. citizens also violate those safe drug packaging statutes, and, as such, will place our children at increased risk.

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